



IFW
PATENT

In the UNITED STATES PATENT and TRADEMARK OFFICE

APPLICANT: Baxter, et al	EXAMINER: Not yet assigned
SERIAL NO.: 10/810,762	ART UNIT: 1614
FILED: March 26, 2004	DOCKET NO.: 7357US01
TITLE: HMB COMPOSITIONS AND USES THEREOF	I certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail addressed to the Commissioner for Patents, Alexandria, VA, on the date shown below.
	<i>Wendy Detwiler</i> 8-20-04 Wendy Detwiler Date

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Enclosed herewith is a Information Disclosure Statement and Form 1449 for the above-referenced patent application.
Also enclosed are:

Fifty-seven (57) references
One (1) return postcard

If any fees are owed, or any credit is due pertaining to this case; please charge that fee or apply that credit to Deposit Account No. 01-0025.

Respectfully submitted,

Ross Products Division of
ABBOTT LABORATORIES
Department 108140/DS1
625 Cleveland Avenue
Columbus, OHIO 43215-1724

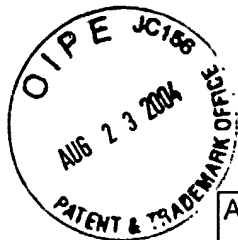
William J. Winter
by William J. Winter
Reg. No. 36,060

Telephone: 614/624-5686
Facsimile: 614/624-3074

Docket: 7357US01

1

2



PATENT

In the UNITED STATES PATENT and TRADEMARK OFFICE

APPLICANT: Baxter et al.	EXAMINER: Not yet assigned
SERIAL NO.: 10/810,762	ART UNIT: 1614
FILING DATE: March 26, 2004	DOCKET NO.: 7357US01
TITLE: HMB COMPOSITIONS AND USES THEREOF	I certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail addressed to the Commissioner for Patents, Alexandria, VA 22313-1450 on the date shown below.
	<i>Wendy DeViller</i> 8-20-04
	Wendy DeViller Date

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In accordance with their duty of disclosure under 37 C.F.R. §1.56, and as authorized and encouraged under 37 C.F.R. §§ 1.97-1.98 and the provisions of MPEP §§ 609 and 707.05(b), Applicants submit herewith certain patent documents, publications and/or other information ("references") which the Patent and Trademark Office may wish to consider in examining the above-identified patent application. The identification of any reference herein is not intended to be and should not be understood as being an admission that such reference necessarily constitutes "prior art" within the meaning of applicable law.

The cited references are listed on attached form PTO-1449.

- ☒ A copy of each cited reference is provided;
- ☐ Copies of cited references are not provided because each has previously been made of record in the parent application, or is otherwise known to be in the Examiner's possession.

The Examiner is requested to review and evaluate each cited reference to make an independent assessment of the materiality of each, if any, to the examination of the above-identified application. The Examiner is requested to ignore any underscoring or highlighting which may have been done because such markings may or may not have any relationship to the subject matter of the present invention. The copies being submitted with this Statement are the best copies available at this time. Applicants respectfully request that (1) the references cited herein be made of record; (2) that the Examiner acknowledge his consideration of each reference by initialing and returning the enclosed copy of the PTO-1449 form; and (3) that such references appear on the printed patent as having been considered on the record.

With regard to payment of a fee:

- ☐ ☒ No fee is due because:
- ☐ ☐ This Statement is mailed within three months of the filing date of this application, or before the mailing date of a first office action on the merits (see 37 C.F.R. §1.97(b)).
- ☐ ☐ Applicants certify that each reference cited in this Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement. (see 37 C.F.R. §1.97(e)).
- ☐ ☒ This Statement is filed after the mailing date of a first Office Action on the merits but before the mailing date of either a final action or a Notice of Allowance (see 37 C.F.R. §1.97(c)) so a fee of **\$180.00** is specified by 37 C.F.R. §1.17(p).

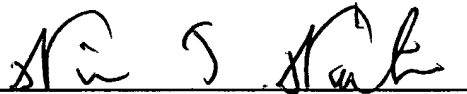
If any fees are owed, or any credit is due pertaining to this case, please charge that fee or apply that credit to Deposit Account No. 01-0025. A duplicate sheet of this page is enclosed.

Ross Products Division of
ABBOTT LABORATORIES
Dept. 108140-DS/1
625 Cleveland Avenue
Columbus, OHIO 43215-1724

Telephone: (614) 624-5686
Facsimile: (614) 624-3074

Docket : 7357US01

Respectfully submitted,



by William J. Winter
Reg. No. 36,060



Sheet 1 of 5

FORM PTO-1449 (Rev. 2032)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 7357US01	Serial No. 10/810,762
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant Baxter, et al.	
(Use several sheets if necessary)		Filing Date March 26, 2004	Group

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)
	5,976,550	11/2/99	Engel, et al			
	6,031,000	2/29/00	Nissen, et al			
	5,457,130	10/10/95	Tisdale, et al			
	4,992,470	2/12/91	Nissen			
	5,028,440	7/2/91	Nissen			
	5,087,472	2/11/92	Nissen			
	5,348,979	9/20/94	Nissen, et al			
	5,360,613	11/1/94	Nissen			
	6,103,764	8/15/00	Nissen			

FOREIGN PATENT DOCUMENTS

Document Number	Date	Name	Class	Subclass	Translation (Yes No)
DE 297 07 308 U 1	4/23/97	Kunz			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	S. Beck, K. Smith, M. Tisdal; "Anticachectic and Antitumor Effect of Eicosapentaenoic Acid and Its Effect on Protein Turnover," Cancer Research 51, 6089-6093, Nov. 15, 1991
	A. Lentsch, P. Ward; "Activation and Regulation of NFkB during Acute Inflammation," Clin. Chem Lab Med, 1999; 37(3): 205-208
	L. Sandberg, P. Miller, J. Fuller, "The Effect of Intensive Training and b-hydroxy-b-methylbutyrate (HMB) on Muscle Glycogen Aconcentration in the Horse," J. Anim. Sci. 76 (Suppl. 1): 175 (1998)
	L. Sandberg, P. Miller, J. Fuller, "Effect of b-hydroxy-b-methylbutyrate on the physiological response to exercise and conditioning in horses." J. Anim. Sci. 75 (Suppl. 1): 198 (1997)
	P. Miller, L. Sandberg, J. Fuller, "The effect of intensive training and b-hydroxy-b-methylbutyrate (HMB) on the physiological response to exercise in horses." FASEB J. 11(3): A290 (1997)
	A. Peterson, M. Qureshi, P. Ferket; "Enhancement of cellular and humoral immunity in young broilers by the dietary supplementation of b-hydroxy-b-methylbutyrate." Immunopharmacology and Immunotoxicology 21(2): 307-330 (1999).
	S. Nissen, J. Fuller, J. Sell, P. Ferket, D. Rives; "The effect of b-hydroxy-b-methylbutyrate on growth, mortality and carcass qualities of broiler chickens." Poultry Science 73: 137-155 (1994).
	J. Fuller, S. Nissen; "Decreasing male broiler mortality by feeding the leucine catabolite b-hydroxy-b-methylbutyrate." Poultry Sci. (Suppl 1) 73:93 (1994)
	S. Nissen, D. Morrical, J. Fuller, "The effects of the leucine catabolite, b-hydroxy-b-methylbutyrate (HMB), on the growth and health of growing lambs." J. Anim. Sci. (Suppl 1) 72: 243 (1994)
	V. Talleyrand, D. Frank, J. Roth, W. Hsu, S. Nissen; "Effect of feeding b-hydroxy-b-methylbutyrate on immune function in stressed calves." FASEB J: A951 (1994)
	M. Van Koevering, D. Gill, R. Smith, F. Owens, S. Nissen, R. Ball; "Effect of b-hydroxy-b-methylbutyrate on the health and performance of shipping-stressed calves." The Oklahoma State Animal Science Research Report, 1993.
	P. Ostaszewski, E. Kozłowska, S. Nissen; "The immunomodulating activity of dietary 3-hydroxy-3-methylbutyrate (HMB) in weaning pigs." J. Anim. Sci. 76 (Suppl 1): 136 (1998), Abstract 525.

EXAMINER

DATE CONSIDERED

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2032)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 7357US01	Serial No. 10/810,762
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant Baxter, et al.	
(Use several sheets if necessary)		Filing Date March 26, 2004	Group

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)

FOREIGN PATENT DOCUMENTS

Document Number	Date	Name	Class	Subclass	Translation (Yes No)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		A. Siwicki, M. Morand, J. Fuller, S. Nissen, K. Kazua, E. Glabski, P. Ostaszewski; "Influence of 3-hydroxy-3-methylbutyrate on specific cellular immune response after in vitro and in vivo immunization with Yersinia ruckeri antifen." J. Anim. Sci. 76 (Suppl 1): 136 (1998). Abstract 527
		A. Siwicki, M. Morand, K. goryczko, P. Ostazewski, J. Fuller, S. Nissen; "Immunomodulating effect of 3-hydroxy-3-methylbutyrate (HMB) on the nonspecific cellular and humoral defense mechanisms in rainbow trout (Oncorhynchus mykiss)." J. Anim. Sci. 76 (Suppl 1): 137 (1998), Abstract 529
		P. Ostaszewski, A. Siwicki, Z. Shrek, B. Balasinska, J. Fuller, S. Nissen; "3-hydroxy-3-methylbutyrate (HMB) fed in the water enhances immune response in young broilers." Poultry Sci. 77 (Suppl 1): 26 (1998), Abstract 96
		M. Van Koevering, H. Dolezal, D. Gill, F. Owens, C. Strasia, D. Buchanan, R. Lake, S. Nissen; "Effects of b-hydroxy-b-methylbutyrate on performance and carcass quality of feedlot steers." J. Anim. Sci. 72: 1927-1935 (1994)
		P. Ostaszewski, K. Grzelkowska, T. Motyl, B. Balasinska, W. Barej, S. Nissen; "3-hydroxy-3-methylbutyrate and 2-oxoisocaproate effect body composition and cholesterol concentration in rabbits." J. Anim. Physiol. and Anim. Nutr. 79: 135-145 (1998)
		S. Nissen, T. Faidley, D. Zimmerman, R. Izard, C. Fisher; "Colostrum milk fat percentage and pig performance are enhanced by feeding the leucine metabolite b-hydroxy-b-methylbutyrate to sows." J. Anim. Sci. 72: 2331-2337 (1994)
		P. Ostaszewski, I. Papet, S. Nissen, F. Glomot, J. Grizard, M. Arnal; "Dietary supplementation of 3-hydroxy-3-methylbutyrate improved catch-up growth in underfed lambs." Ann. Zootech 43: 308 (1994)
		M. Moschini, J. Rathmacher, T. Faidley, J. Sultan, S. Nissen; "Effect of feeding b-hydroxy-b-methylbutyrate (HMB) on leucine and fat metabolism in mammary gland." FASEB J. 7:A&)(1993) Abstract 405
		V. Talleyrand, Z. Zhang, J. Rathmacher, S. Nissen; "Uptake and output of the leucine metabolite b-hydroxy-b-methylbutyrate (HMB) across the leg of pigs." FASEB J. 7:A71 (1993) Abstract 407
		Z. Zhang, V. Talleyrand, J. Rathmacher, S. Nissen; "Change in plasma b-hydroxy-b-methylbutyrate (HMB) by feeding leucine, a-ketioisocaproate and isovaleric acid to pigs." FASEB J. 7:A392(1993) Abstract 2270
		M. Van Koevering, S. Nissen; "Oxidation of leucine and a-ketioisocaproate to b-hydroxy-b-methylbutyrate in vivo." Am J Physiol 262 (Endocrinol. Metab. 25):E27-E31 (1992)
EXAMINER		DATE CONSIDERED

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2032)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 7357US01	Serial No. 10/810,762
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant Baxter, et al.	
(Use several sheets if necessary)		Filing Date March 26, 2004	Group

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)

FOREIGN PATENT DOCUMENTS

Document Number	Date	Name	Class	Subclass	Translation (Yes No)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		P. Flakoll, R. Sharp, D. Levenhagen, C. Carr & S. Nissen; "Reversal of the age-associated decline in protein synthesis, muscle mass, strength and functionality in elderly women through nutritional supplementation of b-hydroxy-b-methylbutyrate (HMB), arginine and lysine. (2003) Manuscript submitted to the Lancet Mid-December, 2002.
		P. E. May, A. Barket, J.T. D'Olimpio, A. Hourihane, N.N. Abumrad; "Reversal of cancer-related wasting using oral supplementation with a combination of b-hydroxy-b-methylbutyrate, arginine and glutamine." Amer. J. Surg. 183: 471-479 (2002)
		S. Nissen, R. Sharp; "Effect of dietary supplements on lean mass and strength gains with resistance exercise: A meta analysis." J. Appl. Physiol. 94: 651-659 (2003)
		S. Nissen, R. Sharp, L. Panton, M. Vukovich, s. Trappe, J. Fuller, Jr.; "b-hydroxy-b-methylbutyrate (HMB) supplementation in humans is safe and may decrease cardiovascular risk factors." J. Nutr. 130: 1937-1945 (2000)
		E. Jowko, P. Ostaszewski, M. Jank, J. Sacharuk, A. Zieniewicz, J. Wilczak, S. Nissen; "Creatine and b-hydroxy-b-methylbutyrate (HMB) additively increase lean body mass and muscle strength during a wight-training program," Nutrition 17: 558-566 (2001)
		R. Clark, G. Feleke, M. Din, T. Yasmin, G. Singh, F. Kahn, J. Rathmacher, "Nutritional treatment for acquired immunodeficiency virus – associated wasting using b-hydroxy-b-methylbutyrate, glutamine and arginine: A randomized, double-blind, placebo – controlled study." J. Parenter. Enteral Nutr. 24: 133-139 (2000)
		L. Panton, J. Rathmacher, S. Baier, S. Nissen; "Nutritional supplementation of the leucine metabolite b-hydroxy-b-methylbutyrate (HMB) during resistance training." Nutrition 16: 734-739 (2000)
		A. Knitter, L. Panton, J. Rathmacher, A. Peterson, R. Sharp; "Effects of b-hydroxy-b-methylbutyrate on muscle damage after a prolonged run." J. Appl. Physiol. 89: 1340-1344 (2000)
		J. Williams, N. Abumrad, A. Barbul; "Effect of a specialized amino acid mixture on human collagen deposition." Annals of Surgery 236(3): 369-375 (2002)
		S. Nissen, R. Sharp, M. Ray, J. Rathmacher, D. Rice, J. Fuller, A. Connelly, N. Abumrad; "Effect of leucine metabolite b-hydroxy-b-methylbutyrate on muscle metabolism during resistance-exercise training." J. Appl. Physiol. 81(5): 2095-2104 (1996)
		M. Vukovich, G. Dreifort; "Effect of beta-hydroxy beta-methylbutyrate on the onset of blood lactate accumulation and VO2 peak in endurance – trained cyclists." J. Strength & Conditioning Res. 15(4): 491-497 (2001)
EXAMINER		DATE CONSIDERED

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2032)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No 7357US01	Serial No. 10/810,762
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant Baxter, et al.	
(Use several sheets if necessary)		Filing Date March 26, 2004	Group#

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)

FOREIGN PATENT DOCUMENTS

Document Number	Date	Name	Class	Subclass	Translation (Yes No)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

			M. Vukovich, N. Stubbs, R. Bohlken; "Body composition of 70-year-old adults responds to dietary beta-hydroxy beta-methylbutyrate similarly to that of young adults." J. Nutr. 131(7): 2049-2052 (2001)
			J. Panton, J. Rathmacher, J. Fuller, J. Gammon, L. Cannon, S. Stettler, S. Nissen; "Effect of b-hydroxy-b-methylbutyrate and resistance training on strength and functional ability in the elderly." Medicine & Science in Sports & Exercise 30(5): S194 (1998)
			S. Nissen, L. Panton, J. Fuller, D. Rice, M. Ray, S. Sharp; "Effect of feeding b-hydroxy-b-methylbutyrate (HMB) on body composition and strength of women." FASEB J. 11: A150 (1997)
			M. Vukovich, N. Stubbs, R. Bohlken, M. Desch, J. Fuller, J. Rathmacher; "The effect of dietary b-hydroxy-b-methylbutyrate (HMB) on strength gains and body composition in older adults." FASEB J. 11:A376 (1997)
			S. Nissen, L. Panton, R. Wilhelm, J. Fuller; "Effect of b-hydroxy-b-methylbutyrate (HMB) supplementation on strength and body composition of trained and untrained males undergoing intense resistance training." FASEB J. 10: A287 (1996)
			J. Rathmacher, S. Nissen, L. Panton, J. Fuller, R. Clark, G. Singh, N. Abumrad; "Safety of a nutritional mixture of b-hydroxy-b-methylbutyrate (HMB), glutamine and arginine in healthy young adults and patients with AIDS." JPEN 23(1): S10 (1999)
			M. Macchi, M. Turner, J. Rathmacher, M. Vukovich; "Influence of co-ingestion of glucose on b-hydroxy-b-methylbutyrate (HMB) metabolism in humans." FASEB J. 13: A909 (1999)
			J. Rathmacher, J. Zachwieja, S. Smith, J. Lovejoy, G. Bray; "The effect of the leucine metabolite b-hydroxy-b-methylbutyrate on lean body mass and muscle strength during prolonged bedrest." FASEB J. 13: A909
			J. Zachwieja, S. Smith, G. Bray, J. Lovejoy, T. Wilt, J. DeLany, J. Rathmacher; Effect of the leucine metabolite b-hydroxy-b-methylbutyrate on muscle protein synthesis during prolonged bedrest." FASEB J. 13: A1025 (1999)
			S. Nissen and N. Abumrad; "Nutritional role of the leucine metabolite b-hydroxy b-methylbutyrate (HMB)." J. Nutr. Biochem. 8: 300-311 (1997)
			R. Kreider, M. Ferreira, M. Wilson, A. Almada; "Effects of Calcium b-hydroxy-b-methylbutyrate (HMB) supplementation during resistance-training on markers of catabolism, body composition and strength." Int. J. Sports Med. 20: 503-509 (1999)
EXAMINER			DATE CONSIDERED

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

